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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/760,061	01/16/2004	Geetha Shankar	061030-0031	1960
24341 7590 06/20/2007 MORGAN, LEWIS & BOCKIUS, LLP. 2 PALO ALTO SQUARE 3000 EL CAMINO REAL PALO ALTO, CA 94306			EXAMINER KANTAMNENI, SHOBHA	
			ART UNIT 1617	PAPER NUMBER
			MAIL DATE 06/20/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/760,061	<b>Applicant(s)</b> SHANKAR ET AL.	
	<b>Examiner</b> Shobha Kantamneni	<b>Art Unit</b> 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-32 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                      | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

### **DETAILED ACTION**

This Office Action is in response to the application filed on 01/16/2004, which claims benefit of 60/440,341 filed on 01/16/2003. Claims 1-32 are pending.

#### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-28, drawn to a method of modulating an Edg-2 receptor mediated biological activity comprising contacting a cell expressing the Edg-2 receptor with a modulator of formula (II), classified in class 514, subclass 359, 360, 364.
- II Claims 29-32, drawn to a method of treating diseases comprising administering a therapeutically effective amount of a compound of claim 1, 2, or 28, classified in class 514, subclass 824, 826.

Inventions I-II are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). In the instant case the inventions have different modes of operation, and are not capable of use together. For, example the mode of operation of modulating an Edg-2 receptor mediated platelet activation is different from the mode of operation of treating cancer.

The above inventions differ as distinct therapeutic methods. The grouped inventions are patentably distinct, a reference which would anticipate, or make obvious,

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any inventions from groups I-II would not necessarily obviate or anticipate, the inventions in any other group. The searches are not co-extensive as indicated by the diverse nature of the subject matter. The search for all inventions would place an undue burden on the office in view of the diversity of treatment methods and the corresponding diversity in the field of search for each. Note that the search involves both patent and non-patent literature.

Because these inventions are independent or distinct for the reasons given above and there would be a serious search and examination burden on the office if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one or more claim remaining in the application. Any amendment of inventorship must be accompanied by request under 37 CFR 1.48(b) and by fee required under 37 CFR 1.17(i).

### **Species Election**

This application contains claims directed to patentably distinct species of the claimed invention:

Applicant is required under 35 U.S.C. 121 to elect

- a. A single disclosed biological activity as in claim 14 or claim 21
- b. A single disclosed disease as in claim 29 such as cancer, acute lung disease, acute inflammatory exacerbation of chronic lung disease, surface epithelial cell injury or cardiovascular disease
- c. A single disclosed modulator of Edg-2 receptor, a compound of formula (II).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Currently, claims 1-28 are generic to a plurality of disclosed patentably distinct species, biological activities; claims 29-32 are generic to a plurality of disclosed patentably distinct species, diseases; and claims 1-32 are generic to a plurality of disclosed patentably distinct species, compounds of formula (II).

The claims read on the employment of various compounds with great diversity of chemical structure, and the treatment of wide variety of diseases or disorder to be treated classified across class 514.

The above species lack the same structure and will have different properties such as binding affinities, solubilities, selectivity's, modes of operation etc. For example, compound of formula (II) wherein X, Y, Z are C(R5)(R5) is structurally distinct from

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compound of formula (II) wherein X, Y are NR<sub>3</sub>, and Z is C(R<sub>5</sub>)C(R<sub>5</sub>). The search for all species of compounds useful in the method herein presents an undue burden on the Office due to their wide-ranging variations in structure and distinct fields of search. It is noted that a reference to individual species would not be a reference to another individual agents under 35 U.S.C. 103.

The search for all different biological activities, and different diseases to be treated in the method herein presents an undue search and examination burden on the Office due to distinct fields of search. It is noted that a reference to individual species would not be a reference to another individual species under 35 U.S.C. 103.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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Because the above restriction/election requirement is complex, a telephone call to the applicant's agent to request an oral election was not made. See M.P.E.P Sec. 812.01.

***Conclusion***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Monday-Tuesday, Thursday-Friday, 8am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Shobha Kantamneni  
Patent Examiner  
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER